



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-------------------------------|---------------------|------------------|
| 10/523,753 | 02/08/2005 | Didier Philippe Robert Schils | JAB1745USPCT | 7955 |

27777 7590 03/29/2006
PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

| |
|----------|
| EXAMINER |
|----------|

BALASUBRAMANIAN, VENKATARAMAN

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1624

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/523,753

Applicant(s)

SCHILS ET AL.

Examiner

Venkataraman Balasubramanian

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 3-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/8/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1, 2 and 10-12, drawn to compound of formula I and the process of making, in the reply filed on 1/12/2006 is acknowledged.

Claims 4-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The traversal is on the ground(s) that the International Search Authority did not make lack of unity of invention and that the restriction requirement did not follow MPEP guidelines for a PCT application entering the national stage. This is not found persuasive for reasons of record in the restriction requirement. As for applicants' traversal, the following apply.

First of all, contrary to applicants' urging that since the International Search Authority did not find lack of unity of the invention, the application entering the national stage should not make any restriction requirement, the PCT application entering the national stage has to be examined based on the guidelines provided under unity of invention in MPEP § 1.475 which are reproduced below:

UNITY OF INVENTION

§ 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said

product, and an apparatus or means specifically designed for carrying out the said process.

- (c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
- (d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).
- (e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

As can be seen from the above, there should be special technical feature to have unity of invention. Lack of such special technical feature had been clearly shown in the restriction requirement made in the previous office action. To repeat:

"The inventions listed as Groups I, II, III, IV, V and VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The following apply.

Where there is lack of unity the requirement for restriction is proper- See MPEP 803.02. The requirement for unity of invention is two-fold: (1) common utility and (2)

Art Unit: 1624

sharing a substantial structural feature disclosed as being essential to the utility. Both these conditions are to be met with. Instant claims do not meet both these conditions.

Invention I-IV and V-VI are independent and distinct from each other because they are directed to process of making structurally dissimilar compounds that lack common core, namely, a pyrimidino core versus benzene core compound. in a mutually exclusive species related as final product and intermediate. Thus, the intermediate does not share the common utility requirement and the substantial structure essential for utility and it is the process for the intermediate is embraced and has bearing on the use. Consequently, the groups require separate prior art searches. They can be made and used independently. Art which may render obvious or anticipate one of the groups would not necessarily do the same for the other group. For example prior art cited in the International Search Report and the Information Disclosure Statement may not be applicable to all the above groups. Each can support a patent as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group.

Invention I, II and III are also distinct and independent. Whereas the invention I relates to compound useful for HIV and its process, inventions I and III relate to various ways of making the same compound each of which is distinct from each other. A prior art which reads on any one of the process may not anticipate or render the other processes obvious. Each invention has to be examined separately."

As seen, the Group I, claims 1-2 and 10-12 relates to a compound (claims 10-120 and a process of making that compound (first recited process claims 1-2) thereby meets the requirement of MPEP § 1.475, (b), category 1.

Claims 3, 4 and 5, which are independent claim relate distinct processes of making compound of formula I. Again, they do not share the special technical feature, namely common utility and the structural portion required for the said utility as the are process claims. If applicants' argument I is based on the formula I as common feature, it is clearly an error. A process parameters decides its patentability even though the product may be known. Otherwise, any process of the compound of formula I can be used to rejection other processes, as obvious variant since applicants appears to suggest equivalency of the processes based on the formula I. See prior art applied.

In addition, it should be noted that applicants have conveniently omitted in (c)-(e) of MPEP § 1.475, particularly (c) which states

- (c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

In the instant case, claims 3-5 embrace distinct multiple processes. Since, the first recited process, claims 1-2, is incorporated in Group I, it is proper to restrict the claims 3-5 and 7-8 as distinct inventions.

As for claims 6 and 9, which are independent, they relate to processes of making an intermediate of formula II. They, as noted above, do not share the common utility and the substantial structural feature essential for the activity namely the triazine core.

Art Unit: 1624

In addition, they are process claims and again the process parameters (limitations) decide their patentability.

As for applicants' argument citing Annex B Rule 13.2, again it should be noted that Group I includes a product and process of making it. The first recited process is included in this group (claims 1-2) and clearly meets the Annex B Rule 13.2. The Annex B Rule 13.2, is not applicable to Group II-VI as they either relate to several process of making compound of formula I (claims 3-5 & 7-8) and process of making compound formula II which is an intermediate.

Finally, applicants have not asserted clearly for record that all the processes of claims 3-5 and 7-8 are equivalent because they make the same product. In which case, prior art used to reject claims 1-2, can then be applied to claims 3-5 and 7-8. The same apply to claims 6 and 9 if applicants were to assert for the record they are equivalent. Prior art disclosing a process of making an intermediate can be applied to these processes.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-2 and 10-12 are under examination.

Information Disclosure Statement

References cited in the Information Disclosure Statement, filed on 2/8/2005 are made of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1624

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 and 10-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Guillemont et al., WO 03/016306.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Guillemont et al., teaches several disubstituted amino-pyrimidines for treating HIV infection, which include instant compound and the process of making. See pages 1-5, formula I and note the definition of various variable groups. Note with these definitions of the variable groups compounds taught by Guillemont et al., include instant compounds. See pages 5-20 for 19 for various preferred embodiments. See page 18, lines 18-28 for the process of making which include instant process. See page 55 for intermediate with E-configuration. See compound 1, examples B1 & B1A, page 67 and page 91 Table 3, compound 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guillemont et al., WO 03/016306.

Teachings of Guillemont et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Guillemont et al., teaches several disubstituted amino-pyrimidines for treating HIV infection, which include instant compound and the process of making. See pages 1-5, formula I and pages 5-20 for 19 for various preferred embodiments. See page 18, lines 18-28 for the process of making which include instant process. Note acetonitrile as a solvent is taught therein. See pages 8-9 for N-oxide, addition salt and quaternary amines of compound of formula I. See page 55 for intermediate with E-configuration. See compound 1, examples B1 and B1A, page 67 and page 91 Table 3, compound 1.

Instant claim 2 differs in requiring optionally changing a salt of the final product to free abase or free base to a salt or making N-oxide or quaternary amines.

Guillemont et al., as noted above in pages 8-9 clearly teaches these as part of the invention and also teaches equivalency of the exemplified compounds (Table1, Table 2 and & Table 3) with those generically recited.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make pyrimidine compounds including their salts, N-oxide and quaternary amine using the teachings of Guillemont et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to

Art Unit: 1624

identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 11 and 12 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 53 and 56 of copending Application No. 10/485,636.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 11 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 54, 55 and 57 of copending Application No. 10/485,636. Although the conflicting claims are not identical, they are

Art Unit: 1624

not patentably distinct from each other because the subject matter embraced in claim 11 is also embraced in claims 54, 55 and 57 of copending application. See also 102/103 rejections for exact overlap of subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM.

The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

Art Unit: 1624

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

Venkataraman Balasubramanian
Venkataraman Balasubramanian

3/17/2006